REMARKS

Status of the claims

Claims 1-10 are pending. Claims 1-10 are rejected. Claims 1-3, 6-7 and 9-10 are amended. Claims 4-5, 8 and 11-31 are canceled. No new matter is added.

Amendments to the claims

Claim 1 is amended to incorporate the limitations of claims 4-5 and 8 to overcome rejections under 35 U.S.C. 102(e) and 103(b), as discussed *infra*. Amended claim 1 now recites that the detected images are enhanced by one of the enhanced imaging methods recited in original claim 4 and that the detected images are displayed on a video monitor external to the image detector. Claim 1 is also amended to clarify that the region of interest (ROI) is illuminated with light from a light source having a wavelength from the red to infrared region of the spectrum. Additionally, the claim is amended to remove the use of imaging with red to infrared light from the preamble to the body of the claim.

Claims 2-3 and 6 are amended to clarify and/or simplify claim language. Claim 7 is amended to remove Markush language as there is no group. Claims 9-10 are amended to depend from amended claim 1. Claims 4-5 and 8 are canceled.

Obviousness-type double patenting

Claims 8-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-11 of U.S. Patent No. 6,353,753. Claims 1-10 are rejected as being unpatentable over claims 1-4 of U.S. Patent No. 6,032,070. Claims 8-10 are rejected over claims 1 and 5 of U.S. Patent No. 6,272,374. Claims 1-10 are provisionally rejected over claims 1, 3-6, 8-9, 11 and 34 of copending application U.S. Serial No. 09/875,497.

Applicants submit herewith four terminal disclaimers in compliance with 37 C.F.R. 1.321(c) to obviate the obviousness-type double patenting rejection.

The 35 U.S.C. §102 rejections

Claims 1-3 and 8-10 are rejected under 35 U.S.C. 102(e) as anticipated by **Crane** *et al.* (U.S. Patent No. 6,230,046). Applicants respectfully traverse this rejection.

Regarding claims 1-3, the Examiner states that **Crane** *et al.* teach a method of optically imaging subsurface anatomic structures and biomolecules in an individual or animal with red light and infrared radiant energy (col. 2, ll. 14-19 and col. 8, ll. 32-62). The Examiner states that a region of interest (ROI) is illuminated with red to infrared light having wavelengths 600 nm to 1100 nm (col. 8, ll. 32-62) and red to infrared light from the ROI is detected with an image detector sensitive to this light (col. 5, ll. 33-49). The detected light may be transmitted light, reflected light, absorbed light, and emitted light (col. 4, ll. 22).

Regarding claims 8-10, the Examiner states that **Crane** *et al.* teach a device comprising a red to radiant infrared light source (co. 8, ll. 32-62, a red and infrared sensitive image detector (col. 5, ll. 33-49) and a means to display detected images (col. 5, ll. 43-45). The Examiner states that **Crane** *et al.* teach that the light source may be light-emitting diodes filtered with a bandpass filter, diode lasers and filtered broadband illumination (col. 10, ll. 7-36). **Crane** *et al.* also teach that the detector may be a CCD device (col. 5, ll. 33-39).

Crane *et al.* teach a helmet imaging system comprising a low level light detector attached to the helmet and a light source for near infrared light, for example. The detector may be that which is used in night vision goggles, including an image intensifier tube, a photomultiplier tube, photodiode or charge coupled device (Abstract; col. 4, ll. 34-42). The image received after illuminating or transilluminating a region of interest is visualized by the observer wearing the helmet through the detector (col. 4, ll. 53-59; Fig. 1) and is formed within the detector by placing a lens in front of a CCD array or a photocathode in an image intensifier tube within the detector (col. 5, ll. 33-37). Also, the image may be formed on a phosphor screen, such as used in a television monitor, as the output of a photomultiplier tube or photodiode which scans the entire field of view (col. 5, ll. 37-45; col. 6, ll. 30-62; Fig. 2).

As amended, Applicants' invention as recited in claim 1, is method of imaging subsurface structures and biomolecules. The method requires illuminating a ROI with light having a red to infrared wavelength using a light source emitting those wavelengths and detecting light from the ROI using an image detector sensitive to this wavelength. The detected image is enhanced using any of the enhanced imaging methods recited in amended claim 1. The enhanced image is transmitted to an external video monitor whereupon the enhanced image is displayed.

As stated by the Examiner, **Crane** *et al.* do not teach the claim element of enhancing a detected image by any of pulsatile enhanced imaging, confocal enhanced imaging, Raman enhanced imaging, laser speckle enhanced imaging, multiphoton interaction enhanced imaging, optical coherence tomography enhanced imaging, time correlated single photon counting enhanced imaging, optical rotary dispersion image, circular dichroism imaging, or polarization enhanced imaging. Also, **Crane** *et al.* do not teach a video monitor or any monitoring means external to the image detector.

Independent claim 8 is canceled. The limitations of dependent claims 4-5 are incorporated into claim 1 and canceled. Claims 2-3, 6-7 and, as amended, claims 9-10 depend directly or indirectly from amended claim 1. These claims further limit the invention with respect to the wavelength and type of light, to including another method step drawn to administering a chromophore and the type of chromophore used and to the light sources and image detectors. The incorporation of the limits of any of these claims into their respective independent claims 1, 7 or 9 would not be anticipated by **Crane** *et al.* because the claim elements not anticipated by **Crane** *et al.* in these independent claims are not limited by claims 2-3, 6-7 or 9-10.

Absent teachings of the image enhancing methods and the use of an external monitor and a controller, **Crane** *et al.* does not anticipate claims 1-10, as amended or canceled. Thus, **Crane** *et al.* is not prior art under 35 U.S.C. 102(b). Accordingly, in view of the amendments and arguments presented herein, Applicants respectfully request that the rejection of claims 1-10 under 35 U.S.C. §102(e) be withdrawn.

The 35 U.S.C. §103 rejections

Claim 4 is rejected under 35 U.S.C. 103(a) as unpatentable over **Crane** *et al.* in view of **Flock** *et al.* (U.S. Patent No. 6,353,753). Applicants respectfully traverse this rejection.

The Examiner states that **Crane** *et al.* teach all the features of the current invention except for the use of the image enhancing methods disclosed in original claim 4. The Examiner states that in the same field of endeavor **Flock** *et al.* teach polarization enhanced imaging enhances contrast (col. 8, ll. 13-38). It would have been obvious to one skilled in the art at the time of the invention to modify **Crane** *et al.* to incorporate polarization enhanced imaging taught by **Flock** *et al.* to further enhance the image.

Applicants' invention is discussed *supra*. **Crane** *et al.* do not anticipate the instant invention. **Crane** *et al.* teach an image detector attached to a helmet worn by the observer (Figure 1). The image is displayed on a lens, a phosphor screen or a television monitor within the image detector and must be viewed there by the observer through the eyepiece in a binocular or monocular fashion (col. 6, ll. 61-63). Thus, even if one of ordinary skill in the art is motivated to use linearly polarizing filters to enhance image contrast, the inclusion of such filters is not Applicant's invention and therefore cannot render amended claim 1, which incorporates original claim 4, obvious. Therefore, the invention was not obvious to one of ordinary skill in the art at the time the invention was made. Accordingly, in view of the amendments and arguments presented herein, Applicants respectfully request that the rejection of claim 4 under 35 U.S.C. §103(a) be withdrawn.

Claims 5-7 are rejected under 35 U.S.C. 103(a) as unpatentable over **Crane** *et al.* in view of **Svetliza** (U.S. Patent No. 6,178,340). Applicants respectfully traverse this rejection.

Regarding claim 5, the Examiner states that **Crane** *et al.* teach all the features of the current invention, including a TV monitor, except for expressly stating that the images from the infrared sensitive detector are displayed on a video monitor. The Examiner states that **Svetliza** is in the same field of endeavor and expressly teaches that

the images from the infrared sensitive image detector are displayed on a video monitor, such as an RGB video monitor (col. 5, ll. 19-29). While **Crane** *et al.* state the use of a TV monitor, **Svetliza** is used because of the expressed statement of a display video monitor. Regarding claims 6-7, the Examiner states that **Svetliza** teaches the step of adding an exogenous chromophore to the region of interest. The chromophore may be indocyanine Green or 6-aminolevulinic acid (col. 5, ll. 64-67; col. 6, ll. 1-22).

Svetliza teaches a stereoscopic infrared viewer to improve visualization of blood vessels. The viewer contains an IR light source, two IR video sensors and a screen. A double image is imposed on the viewer and the observer wears blue-red eyeglasses to create the three-dimensional image from the double image on the viewer (Abstract). The viewer may display color images from color infrared sensors on a LCD screen or, when TV cameras are used as sensors, the black and white images are converted to color via a color space converter and displayed on an RGB video monitor (col. 4, ll. 48-51; col. 5, ll. 4-21). Additionally, as stated by the Examiner, **Svetliza** teaches using a chromophore to enhance visualization of blood vessels.

Applicants' invention is discussed *supra* where the limitations of dependent claim 5 are incorporated into claim 1. Claim 5 is canceled. **Crane** *et al.* is discussed *supra*. Additionally, **Crane** *et al.* teach a helmet imaging system using light sources and image detectors which are known and standard in the art and which are utilized in the manner for which they are designed (col. 6, ll. 36-45).

As known in the art the television monitor would be positioned appropriately within the image detector. The image is serially scanned, such as with raster scanning, and each position of the image is registered with the position of the image on the television monitor (col. 5, ll. 39-45). Applicants maintain that **Crane** *et al.* does not teach an external monitor. Any suggestion or motivation found in **Svetliza** to use any type of video monitor would require one of ordinary skill in the art to incorporate such a monitor within the image detector in **Crane** *et al.* This is not Applicant's invention and, therefore, cannot render amended claim 1, which incorporates original claim 5, obvious.

Furthermore, the teaching in **Svetliza** is color infrared imaging or conversion of infrared images to color and display with an RGB video monitor. At the

time of the instant invention, to view infrared images, such as obtained with telescopes or night vision binoculars or monoculars or IR cameras, as color images required that the images be fed to an external RGB video monitor. Applicants submit that the Gen III night vision goggles used in **Crane** *et al.* have not yet been adapted to incorporate color imaging within the image detector.

The helmet imaging system in **Crane** *et al.* is designed to be portable, to keep the operators hands free to work on an individual and to insure that the image detector is always focused on the ROI when the operator wishes to view the ROI, even if the operator is moving, because the operator observes the ROI on the display in the image detector. As such, any external image display means, e.g., a video monitor, would be precluded. The operator would have to remove the helmet to view the display and could not directly view the region of interest while attending to the individual. There is no expectation of success in making this modification.

Claims 6-7 depend from amended claim 1 and further limit the method by including the step of administering a chromophore. Applicants reiterate that **Crane** *et al.* do not anticipate all the claim elements in amended claim 1. The combination of **Crane** *et al.* with **Svetliza** to modify the method by including administration of a chromophore does not remedy this defect. Thus, **Crane** *et al.* in combination with **Svetliza** cannot render the instant invention obvious.

Thus, Applicants submit that, lacking a teaching or suggestion of all the elements of the claimed invention and a reasonable expectation of success, obviousness has not been established. Therefore, the invention was not obvious to one of ordinary skill in the art at the time the invention was made. Accordingly, in view of the amendments and arguments presented herein, Applicants respectfully request that the rejection of claims 5-7 under 35 U.S.C. §103(a) be withdrawn.

This is intended to be a complete response to the Office Action mailed March 25, 2004. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution. Applicants enclose herewith four Terminal Disclaimers under 37 C.F.R. 1.321. Please debit the $220

fee for these four Terminal Disclaimer or any other applicable fees due from Deposit Account No. 07-1185 on which Applicant's counsel is allowed to draw.

Respectfully submitted,

Date: June 8, 2004

Benjamin Aaron Adler, Ph.D., J.D.
Registration No. 35,423
Counsel for Applicant

ADLER & ASSOCIATES
8011 Candle Lane
Houston, Texas 77071
(713) 270-5391 (tel.)
(713) 270-5361 (facs.)
badler1@houston.rr.com